

PATENT COOPERATION TREATY

(14)

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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RECEIVED

19-12-2001

FENSTER & Co.

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19-12-2001

Docketed by: JB

PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference 110/01507		REPLY DUE within 3 month(s) from the above date of mailing	
International application No. PCT/IL00/00471	International filing date (day/month/year) 03/08/2000	Priority date (day/month/year) 27/01/2000	
International Patent Classification (IPC) or both national classification and IPC A61B17/70			
Applicant DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. et al.			

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☐ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain document cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **27/05/2002**.

Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer / Examiner Josten, S 2338 +49 89 2399 2348 Formalities officer (incl. extension of time limits) Novoa, C Telephone No. +49 89 2399 2718
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International application No. PCT/IL00/00471

I. Basis of the opinion

1. With regard to the **elements** of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"):

Description, pages:

1-27 as originally filed

Claims, No.:

1-106 as originally filed

107-119 as received on 29/08/2001 with letter of 27/08/2001

Drawings, sheets:

1/13-13/13 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

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International application No. PCT/IL00/00471

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☒ the entire international application,
- ☐ claims Nos. ,

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
 - ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-106 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet
 - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☒ no international search report has been established for the said claims Nos. 107, 113-119.
2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- ☐ the written form has not been furnished or does not comply with the standard.
 - ☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees, the applicant has:

- ☐ restricted the claims.

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- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:
3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-106, 107, 113-119.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claim 1 is not clear as to the wording "in non-axial orientation in a bone". It is totally unclear what the technical features of the implant are which are intended to be defined by this feature. As can be seen from figure 1 of the present application, **anchoring** of the implant 200 takes place around the expanding tip and along the bars. The bar 212 as shown in figure 1, however, clearly extends in the axial direction of the vertebra 204 when being expanded (- the axis of a single vertebra is defined by the axis of the vertebral column -) thus creating an inconsistency between figure 1 and what might be meant by the wording of present claim 1. Figure 1 of the present application clearly shows implants which are **anchored** in the vertebra in an axial orientation in said vertebra.

If, however, the wording "in non-axial orientation in a bone" is intended to define the position of the implant in a bone, then the technical features of the implant should be clearly indicated which allow to define the orientation of the implant. In that case, the wording "in non-axial orientation in a bone" appears to relate to a feature of the use of the implant but not to a technical feature of the implant per se. The same applies to claims 2 to 4.

For the above-mentioned reasons it is at the moment not possible to do a sensible examination.

Re Item IV

Lack of unity of invention

2. See the two groups of inventions indicated in form 405, ie. the preceding communication. Claims 108 to 112 each relate to the second group of inventions for which the applicant did not wish to pay additional fees.